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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,582	11/06/2000	Frank M. Jordan	Immusonic-004	9647

7590 11/03/2004

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/707,582	JORDAN ET AL.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *the amendment of 17MAY2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9-17 and 25-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9-17 and 25-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 7, 9-17, and 25-37 are pending.

2. Claims 7, 9-17, and 25-37 are rejected.

Response to Arguments

3. Applicants' arguments filed May 17, 2004 have been fully considered but they are not persuasive. Applicants present the following arguments. First, applicants argue that the Marciani patent application publication is essentially only a rehash of the prior art, in particular β-1,3-glucans are immunostimulants. Second, applicants purport that Marciani fails to teach or even suggest that β-1,3-glucans and β-1,6-glucans can be used to upregulate the expression of the humoral response, namely B cells, on antigen presenting cells. Third, applicants allege that the Marciani patent publication would not lead a skilled artisan to know or even suspect that certain β-1,3-glucan-containing compositions would cause the upregulation of B7 family of co-stimulatory molecules.

4. First, applicants argue that the Marciani patent application publication is essentially only a rehash of the prior art, in particular β-1,3-glucans are immunostimulants. The prior art reference of Marciani provides the skilled artisan with a method of expressing inter alia B cells as well as cell-mediated immune response, namely T cells, (see paragraph 5). In addition, Marciani, specifically teach of the administration of the preferred polysaccharides of β-1,3-glucans and β-1,6-glucans in order to activate the immune system, (see paragraph 5,7, 38, and 39). One having

ordinary skill in the art is provided with the necessary motivation to administer the known upregulating agents of β-1,3-glucans and β-1,6-glucans to illicit an immune response via the expression of B cell responses.

5. Second, applicants purport that Marciani fails to teach or even suggest that β-1,3-glucans and β-1,6-glucans can be used to upregulate the expression of the humoral response, namely B cells, on antigen presenting cells. The Marciani patent application publication teaches and suggests to the skilled artisan to administer the immunomodulatory polysaccharide adjuvants of β-1,3-glucans and β-1,6-glucans, (see paragraphs 5 and 7). Marciani also disclose that on the surface of the APCs, such as dendritic cells and macrophages, are expressed, processed antigens that are recognized by T cells, (see paragraph 6). Marciani also state that B cells are stimulated by processed antigens by the APCs to generate antibodies, (see paragraph 6). From these findings, the skilled artisan provided with explicit teachings and ample motivation to express an increased number of B molecules, which would obviously include B7 molecules with the administration of β-1,3-glucans and β-1,6-glucans. Moreover, Marciani also disclose oral administration of these glucans (see paragraphs 134 and 137).

6. Third, applicants allege that the Marciani patent publication would not lead a skilled artisan to know or even suspect that certain β-1,3-glucan-containing compositions would cause the upregulation of B7 family of co-stimulatory molecules. This allegation is not found convincing for the following reasons. Marciani provides evidence to the fact that the administration of β-1,3-glucans and β-1,6-glucans

upregulates the B molecules and even T cell-mediated immune responses. Although Marciani are silent to the expression of a particular family, such as B7 molecules, the Marciani patent application publication teaches of increased expression of B cells and T cells with the administration of co-stimulatory molecules of glucans. As a result, this provides motivation to increase a particular family of B cells, such as B7 molecules. It appears that applicants have shed more light on an already inherent biochemical mechanism. The fact remains that Marciani teach of the increased expression of B cells when β-1,3-glucans and β-1,6-glucans are administered. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. *In re Susi*, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merk & Co. vs. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Claim Rejections - 35 USC § 112

7. The rejection of claims 7-17 and 24 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the upregulating agents of the glucan-containing compositions of β-1,3-glucans and β-1,6-glucans, does not reasonably provide enablement for other types of upregulating agents is removed in response to the amendment of May 17, 2004.

8. The rejection of claims 22-24 recite the limitation "the glucan containing composition" or "glucan-containing composition" in line 1 of these claims is rendered moot in view of the cancellation of these claims with the amendment of May 17, 2004.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 7, 9-17, and 25-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marciani only teaches of the upregulation of B cells, see U.S. Patent Application No. US 2002/0150585. Marciani teach that it is known in the art that

polysaccharide compounds, such as β-1,3-glucans and β-1,6-glucans, are shown to stimulate the immune system. The antigen-presenting cells have specific cell-surface-receptors, which recognize and bind the sugar moieties of these and other polysaccharides. Marciani provides examples of the antigen-presenting cells, such as dendritic cells, which are shown to take up antigens and process them to small peptides in endolysosomes. Marciani further teach that the processed antigens are expressed on the surface on the surface of the antigen-presenting cells, which are subsequently shown to stimulate B cells by the processed antigens in order to generate antibodies, (see from columns 1 and 2, paragraph 6). The claims differ from the prior art reference of Marciani by reciting a specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species would have similar properties and, thus, the same use as the genus as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. *In re Susi*, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merk & Co. vs. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

13. Moreover, the determination of dosages and pharmaceutical preparations as well as modes of administration is well within the level of the skilled artisan. Despite the fact that Marciani are silent to the expression of B7 molecules, it would have been obvious

to one having ordinary skill in the art that all B cells would be stimulated and upregulated with the administration of polysaccharides as disclosed by Marciani. Accordingly, the instant invention is made obvious in view of Marciani.

Obviousness-type Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 7, 9-17 and 25-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 and 15-23 of copending Application No. 10/630,143. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the prior art reference teach of method of expressing increased numbers of B7 molecules with an upregulating agent on antigen presenting cells as well as microparticules of β-1,3-glucans and β-1,6-glucans.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (703) 872-9306.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER
Tech Ctr. 1614
October 29, 2004